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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/763,153	02/20/2001	Lihua Huang	X-12279	3455

7590 03/26/2003

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EXAMINER
MOORE, WILLIAM W

ART UNIT	PAPER NUMBER
1652	

DATE MAILED: 03/26/2003

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	09/763,153	HUANG ET AL.	
	Examiner	Art Unit	
	William W. Moore	1652	

-- *The MAILING DATE of this communication appears on the cover sheet with the correspondence address* --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☐ Responsive to communication(s) filed on _____ .

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) 1-8 is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) 1-8 is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

11)☐ The proposed drawing correction filed on _____ is: a)☐ approved b)☐ disapproved by the Examiner.

If approved, corrected drawings are required in reply to this Office action.

12)☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

13)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____ .

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

14)☒ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).

a)☐ The translation of the foreign language provisional application has been received.

15)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

1)☒ Notice of References Cited (PTO-892)
2)☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3)☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____ .
4)☐ Interview Summary (PTO-413) Paper No(s). _____ .
5)☐ Notice of Informal Patent Application (PTO-152)
6)☐ Other: .

DETAILED ACTION

National Stage Examination Under 35 U.S.C. §371

It is noted that this application has entered the national stage from the international application PCT/US99/11969 after compliance with 35 U.S.C. §371 and it appears to claim subject matter disclosed in prior the provisional U.S. Application No. 60/087,585 filed June 1, 1998. A reference to both of these prior applications must be inserted as the first sentence of the specification of this application or in an application data sheet (37 CFR 1.76), if applicant intends to rely on the filing date of the prior application under 35 U.S.C. 119(e) or 120. See 37 CFR 1.78(a). For benefit claims under 35 U.S.C. 120, the reference must include the relationship (i.e., continuation, divisional, or continuation-in-part) of all nonprovisional applications.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. §102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (a) the invention was known or used by others in this country, or patented or described in a printed publication in this or a foreign country, before the invention thereof by the applicant for a patent.

Claims 1, 3, 5, 7 and 8 are rejected under 35 U.S.C. §102(a) as being anticipated by Katsumi et al., 15 May 1998, Blood, Vol. 91, pages 3784-3791, cited and supplied for Applicant in the International Search Report and made of record herewith.

Katsumi et al., published two weeks before the June 1, 1998 filing date of Applicant's provisional U.S. application disclose, Table 1 and Figure 1 at page 3785, the recombinant preparation of an isolated human Protein C polypeptide which comprises a light chain and a truncated heavy chain, lacking as many as 60 amino acids of the native heavy chain's carboxyl-terminal region. Katsumi et al. further disclose, see Table 2 at page 3787, that several forms of the expressed human Protein C having a truncation of the heavy chain are activated and also disclose, in the **Materials and Methods** spanning pages 3784 and 3785, preparation of recombinant DNAs encoding human Protein C polypeptides having heavy

chain truncations, and an expression vector, pED, comprising the recombinant DNAs, as well as a mammalian recombinant host cell transformed with the expression vector. Katsumi et al. specifically disclose preparation of a human protein C polypeptide having a particular heavy chain truncation, PC416, see Figures IA and 2B and Table 2. Thus the disclosure of Katsumi et al. meets all limitations now stated in claims 1, 3, 5, 7 and 8.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. §103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

Claim 6 is rejected under 35 U.S.C. §103(a) as being unpatentable over Katsumi et al. as applied to claims 1, 3, 5, 7 and 8 above.

Claim 6 depends from claim 1 and a claimed method of treating thrombotic disorders utilizing a human protein C polypeptide having a heavy chain truncation taught by Katsumi et al. is considered to obvious to one of ordinary skill in the art at the time the invention was made because Katsumi et al. show , in Table 2, that the entire range of heavy chain truncation variants about the PC416 position have activity and because such an artisan at that time would have had a reasonable expectation that such heavy chain truncation variants, including the PC416 heavy chain truncation variant, would be efficacious when administered to a patient in a method of treating thrombotic disorders, vascular occlusive disorders, and hypercoagulable states where these disorders and states invoke the function of native Protein C in the human circulatory system.

Claims 2 and 4 are rejected under 35 U.S.C. §103(a) as being unpatentable over Katsumi et al., as applied to claims 1, 3, 5, 7 and 8 above, in view of Ehrlich et al., 1989, The Journal of Biological Chemistry, Vol. 264, pages 14296-14304, cited and supplied for Applicant in the International Search Report and made of record herewith.

The teachings of Katsumi et al., discussed above, are taken as before, particularly their teaching of the PC416 human protein C polypeptide having a heavy chain truncation and a DNA sequence encoding same. Because Katsumi et al. had used a Protein C-encoding cDNA transcribed from a different human allele, the teaching of Ehrlich et al. is now cited. Ehrlich et al. teach, pages 14299-14303, the cloning of a cDNA comprising the nucleic acid sequence of SEQ ID NO:2 herein. It would have been obvious to one of ordinary skill in the art at the time the invention was made to replace the cDNA of Katsumi et al. with the cDNA of Ehrlich et al. in the preparation of a PC415 human Protein C polypeptide heavy chain truncation, just one amino acid shorter than the PC416 human Protein C heavy chain truncation, meeting limitations of claims 2 and 4 herein. This is because such an artisan would have been aware that the two cDNAs are interchangeable in their coding capacity up to that point and also because such an artisan would have had a reasonable expectation that a PC415 truncation variant would function just as well as the PC146 variant of Katsumi et al. where table 2 of Katsumi et al. shows that slightly shorter truncations have better activity than the PC416 truncation variant.

Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to William W. Moore whose telephone number is 703.308.0583. The examiner can normally be reached between 9:00AM-5:30PM EST. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Ponnathapura Achutamurthy can be reached at 703.308.3804. Further fax phone numbers for the organization where this application or proceeding is assigned are 703.308.4242 for regular communications and 703.308.0294 for After Final communications. The examiner's direct FAX telephone number is 703.746.3169. Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 703.308.0196.

William W. Moore

William W. Moore
March 21, 2003